Genome editing and international regulatory challenges: Lessons from Mexico

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Summary

While human genetic modification has long been the subject of bioethical attention, the advent of new 'genome editing' techniques such as the CRISPR/Cas system has provoked renewed interest in this area. The comparative efficiency and precision of these techniques greatly increases their value to research as well as the scope of possible applications. Genome editing, in combination with stem cell science, has the potential to produce a new generation of somatic gene therapies. It is perhaps, however, the fact that these techniques make reproductive germline genetic modification a real and practicable possibility that has sparked scientific and ethical attention.

While a moratorium on genome editing research, such as that called for by some in the wake of the first reported use of CRISPR in human embryos, may not be an effective or justified solution to such concerns, questions remain as to how such

technologies should be regulated. A significant issue is that the attention given to genome editing techniques and their therapeutic potential is likely to stimulate demand from patient groups, especially in the case of conditions for which there are currently no effective treatments – as has happened with stem cell therapies. This, together with the relative ease of application of genome editing techniques, creates the very real possibility that (as for stem cells) in the absence of adequate regulation or oversight, clinical treatments using genome editing, whether somatic or reproductive, may be offered ahead of sufficient testing of safety and efficacy. This is likely to be most problematic in countries where unlicensed therapies are already prevalent; Mexico, for example, is a known destination for stem cell 'treatments', at least some of which are offered without rigorous scientific validation. Moreover, the phenomenon of medical tourism means that this is not just a problem for these countries but one that requires global cooperation to achieve an effective transnational regulatory solution.

In this paper we consider the ethical and regulatory challenges presented by genome editing technologies and the problem of 'rogue' therapies, using the Mexican context as a case study to illustrate the potential pitfalls and issues that will need to be addressed to achieve effective governance in this area. Drawing on lessons learned from other areas of science and other jurisdictions, we suggest some principles that may help to develop an appropriate framework for regulating this fast-moving area of science.

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1. INTRODUCTION

1.1 The ethics of genetic modification: 40 years of debate

Genetic modification first seriously came to public attention in the early days of recombinant DNA. The Asilomar conference in 1975, convened in response to growing public and scientific concerns over the use of recombinant DNA technology, was seen as a landmark that brought genetic engineering into the spotlight even as it secured scientists' license to carry on developing this work[1–3]. Yet although Asilomar enabled the blossoming of molecular genetics that has since had a transformative effect on biology and biotechnology, ethical and social concerns, particularly regarding the prospect of human genetic engineering, continued to provoke ongoing debate.

Fast forward 40 years and the big picture looks surprisingly similar: genetic engineering is seldom out of the headlines, and human genetic modification remains the subject of passionate debate. Genetic modification is by now a familiar topic for bioethics, but its current prominence is the result of a new wave of technologies known as 'gene editing' or 'genome editing', that has provoked renewed interest in these issues, and human germline genetic modification (HGGM) in particular.

The theoretical issues surrounding HGGM are not new; they have been explored extensively elsewhere[4–8] and we will not review them here. Our aim in this paper is to address the ethical and regulatory issues that we see as of most current importance in relation to genome editing, both as a research tool and for potential clinical application. Although the most appropriate regulatory distinction would seem to be between research and clinical application, research that seems to be *directed at* achieving eventual HGGM applications has been seen as a special case; we suggest, however, that there are insufficient grounds to rule out such research while the ethical debate remains unresolved. In relation to possible applications, of most concern is the potential for treatments based on gene editing techniques to be offered prematurely and to find ready customers on the international health market, ahead of adequate tests to determine safety and efficacy. We suggest that global cooperation across a number of spheres of

regulation, not only gene editing itself, is required to address this issue.

1.2 Genome editing: same goals, new methods

Foremost among the new generation of what are being called 'gene editing' or 'genome editing' technologies is the CRISPR/Cas system[9] (henceforth referred to as CRISPR), which uses a guide RNA together with a nuclease enzyme that cuts the DNA to achieve specific targeted modification of the desired sequence. Other tools such as ZFNs[10] and TALENs use DNA-binding proteins for the targeting step, but the principle is similar.

The main factor that has transformed the scientific landscape and hence the issues of ethical concern in practice is the ease of use and efficiency that gene editing technologies represent. Previous methods available for targeted genetic modification had a much lower efficiency. This meant that to create genetically modified mammals, such as mice, the gene targeting step had to be done in cells *in vitro*, to allow the few cells out of thousands that might bear the desired modification to be selected; these cell lines could then be inserted into embryos to produce 'chimeric' organisms that would carry the modification in some of their cells, and breeding and back-crossing the chimeras would produce subsequent generations all carrying the modified gene.

This process of genetic modification has been used successfully for years to create transgenic mice, providing valuable research tools[11]; it was clearly unacceptable, however, for use in humans. The impracticalities of carrying out HGGM using these techniques meant that bioethicists could 'agree to disagree': that whether they opposed or accepted the possibility of HGGM in principle, all could agree that the methodological and safety obstacles were such that it ought not to be attempted in practice.

By contrast, the high efficiency of CRISPR means that the method can be applied directly to an embryo to create the genetic modification in some or all of that embryo's cells; if the embryo is allowed to develop, the resulting human being would then carry that modification. He or she would not be a 'chimera' (with

cells from two distinct origins), though might be a 'mosaic' (where cells of the same organism differ genetically), if the CRISPR modification does not take effect identically in all cells of the embryo. The new technique removes many of the obstacles of the previous method and, together with advances in other areas such as whole-genome sequencing and assisted reproductive technologies, suddenly makes HGGM a much more feasible prospect.

2. ETHICAL ISSUES

2.1 CRISPR and human germline genetic modification

While the CRISPR method was published in 2012, public interest and concern over the technique surged in 2015, when in April a paper reported the use of CRISPR to modify human embryos[12]. Around the same time, two groups of scientists published commentaries, in *Science*[13] and *Nature*[14] respectively, each calling for restrictions on particular uses of gene editing technology in relation to human embryos. One group advocated for a voluntary moratorium on all gene editing of embryos, saying that "scientists should agree not to modify the DNA of human reproductive cells", for fear that other forms of gene editing research would be 'tarred with the same brush', impeding valuable science[14]. The second was more moderate, focusing on specifically on clinical reproductive use and calling for measures to "[s]trongly discourage, even in those countries with lax jurisdictions where it might be permitted, any attempts at germline genome modification for clinical application in humans"[13]. They were united, however, in identifying the use of gene editing to create children as impermissible at the present time.

One question that arose in relation to the use of gene editing in embryos was whether this actually constituted HGGM in the sense to which most ethical concerns attach, that is, modifying the genome in a way that will be heritable and affect future generations. These were the fears suggested by the plea of one of the above-mentioned groups, Lanphier and colleagues – "Don't edit the human germline"[14]. As well as their worries about public perceptions of HGGM getting in the way of other uses of gene editing, they cited concerns over the

eventual prospect of "non-therapeutic genetic enhancement" as a reason to oppose any form of germline genetic modification, including embryo research.

According to the scientific definition, the germline includes germ cells and any cell that could give rise to them. This could be seen to include not only gametes and pluripotent cells of the early embryo but, given the capacity to produce gametes *in vitro* from induced pluripotent stem cells, potentially any somatic cell – a broad definition indeed.

What we are really concerned about in ethical discussions of 'germline genetic modification', however, is the creation of genetically modified human beings – not whether some cell in a dish that could potentially one day become or give rise to a cell that might contribute to becoming a human being is modified, but whether that potential is ever actualised.

In the case of the first paper that reignited the controversy, the embryos used in fact had no potential ever to become persons, as they were incapable of developing beyond a relatively early stage. Comments by the authors indicated that non-viable embryos had been chosen in order to address ethical concerns about germline genetic modification[15]. (The research was in fact criticised scientifically on those grounds, since the abnormality of the embryos used might limit the usefulness of the results for understanding gene editing in normal embryos.)

But even a viable embryo will not develop into a human being unless implanted. If what we are concerned about is the production of genetically modified children, what is important is not whether human embryos are modified, but whether those embryos are ever destined to become children and whether we enable them to do so by implanting them. Hence, many argued, the distinction ought to be drawn between research versus reproductive uses, rather than between somatic and germline modification.

This distinction, and the fact that gene editing could still lead to much valuable research not aimed at reproductive uses, was one that responses aimed at policy were most concerned to emphasise. The various statements produced by UK bioscience funders[16], the Hinxton Group[17,18] and the National Academies

international summit meeting in December 2015[19] all stressed the importance of basic gene editing research and that this should not be impeded by concerns over application.

2.2 Steps towards HGGM: the slippery slope revisited?

Nevertheless, the prospect of ongoing research with gene editing in embryos, including reports of the first such experiments licensed by the UK's national regulator, the Human Fertilisation and Embryology Authority[20], has continued to fuel debate. Further 'slippery slope' concerns were provoked by the recent publication of a study reporting attempts in human embryos to edit a gene that could confer HIV resistance[21].

The slippery slope concern in its wide form often attaches to an entire range of basic research that (in the case of gene editing) *could* eventually contribute to producing a genetically modified human but could also be used for many other valuable purposes, rendering this objection irrelevantly broad. This particular objection, however, sheds a somewhat different light on the slippery slope problem. The two-dimensional ethical slope, with a seemingly innocuous step at the top and an inevitable slide down to moral bankruptcy at the bottom, is not a very good metaphor for the reality of how science develops. Science, with its myriad possibilities, is more like a rubber-sheet representation of the topology of the universe, with three-dimensional bumps and dips: from any given point, we can roll in many different directions, only some of which might or ought to cause concern.

In this case, the HIV-resistance research was seen as 'rolling' in an alarming direction, where other forms of embryo research were not. Commentators perceived a distinction between different kinds of embryo research: basic research "answering questions intrinsic to embryology"[21] was deemed acceptable, whereas this was seen as a step directly towards human germline genetic modification. The Hinxton Group Statement also recognised "research to inform the plausibility of developing safe human reproductive

applications"[17,18] as a distinct category, though did not explicitly comment on its acceptability as such.

The ethical question this raises bears considering, given that embryo gene editing, including research that might pave the way towards HGGM, is likely to increase in the near future: If we consider it is, or it *might be* wrong to do X, is it wrong to do steps A, B and C that can lead to X?

One response might be that A, B and C don't have to lead inevitably to X: although X might require us to first do ABC, doing ABC does not require that we *must* then do X. If steps ABC don't obviously lead anywhere else useful, however, there would seem to be little point in doing them *other than* to lead to X. If we have already decided that we should not do X, then this allows us to contend that we ought not to do ABC on the grounds that it represents a waste of resources and effort; that there are better things to do all things considered; and that the goals of science would be better served and resources better used by pursuing other forms of research. The argument gains further strength when the research in question involves human embryos: as these are a limited and valuable resource invoking moral sensitivities, it is seen as particularly unjustified to use them for pointless or frivolous experiments – "just playing with human embryos"[22].

This line of argument holds, however, only in the case where we have concluded that X would be wrong. With respect to HGGM, it is not clear that this is the case. Scientists and ethicists agree that using gene editing to create GM humans *now* would be wrong, whether simply premature for reasons of safety or because creating a GM human is intrinsically wrong. It is by no means universally agreed, however, that it will *always* be wrong: the bioethical jury is still out, with strong advocates on both sides. The most we can say, with respect to HGGM, is that we have not yet resolved the question of whether it is right or wrong to do X. Indeed some lines of argument hold that it would be wrong *not* to do it, that if HGGM will lead to benefits such as improving human welfare, we have a moral obligation to pursue it. In this situation, it is far from clear that it is wrong to do steps ABC

Thus, although some described the HIV-resistance experiment as "the science… going forward before there's been the general consensus after deliberation that such an approach is medically warranted"[22], the science would seem to be a necessary part of determining whether this approach is *medically* warranted; what we have not yet determined is whether it is ethically warranted, but while the ethical issues remain in question, scientific investigation to answer the scientific questions is not unjustified.

2.3 A market for gene therapies

Many more questions remain to be answered in determining whether and how we as a society should proceed towards eventually using gene editing to create genetically modified human beings. We suggest, however, that the biggest concern in relation to gene editing at the present time is not the possibility of eventual HGGM and whether we should be taking small steps towards it as part of a scientifically well-defined process that would adequately characterise the technical risks at the same time as engaging in appropriate social discourse over the ethical concerns. The greater worry is that there may be those who, seeing a market opportunity, are willing to take great leaps (or at least claim that they are) and start offering products or treatments based on (or under the banner of) gene editing.

That such a market opportunity exists, and those willing to take advantage of it, is aptly demonstrated by that other exemplar of ethically contested biotechnology: stem cell science. While ethical debate over stem cells has focused more on research than on application (the main issue of course being around the destructive use of human embryos in generating embryonic stem cell lines), it is another area which holds great therapeutic promise that is, however, still largely in the developmental phase. Of course some forms of stem cell therapy, notably haematopoietic cell therapy in the form of bone marrow transplantation, have been in use for many years; but other cell therapies, including interventions using both embryonic and tissue-derived stem cells, are still at an early stage. Despite this, however, there has been a proliferation of

clinics offering treatments that they claim are based on these still-unproven techniques[23,24]. Often these clinics advertise direct to consumers, offering generic treatments for an improbably wide range of conditions, based on anecdote and testimony rather than scientific evidence, without any apparent intention to collect data on their further use in order to contribute to a scientific evidence base, and at considerable cost to patients[25,26].

This phenomenon is a widely recognised one, and of great concern to scientists and ethicists alike[27–29]. Not only does it illustrate the possibility for the same to occur with gene editing but, because somatic gene therapy will also require stem cell technology, an easy opportunity exists for the same operators to branch out and add gene editing to their catalogue. Moreover, attempts at reproductive germline editing would also be possible: "the ease of use and accessibility of the technology make it ripe for exploitation by rogue or charlatan organizations, especially in jurisdictions where fertility clinics… are loosely regulated"[30].

To be clear, the concern here is not that rogue operators offering insufficiently-tested gene editing treatments will bring about some unmitigated population-wide disaster to the human genome at large. Most likely, as with some of the 'stem cell treatments' currently on offer, they will not work at all, or if they work in ways so as to have effects other than expected, these will be limited to the patient themselves.

Of course the negative consequences for patients themselves are something we should be concerned to avoid, both the exploitation and waste of resources that occurs when patients are induced to spend their money (and as in the case of stem cell interventions, these procedures are likely to carry a high price tag) and invest hope and effort into bogus treatments as well as the potential for direct harm caused by insufficiently-tested interventions.

But the possibility of gene editing 'treatments' being offered ahead of adequate scientific validation may also have more far-reaching harmful consequences. The provision of interventions that are ineffective or downright dangerous is liable to result in a loss of faith in science, damage the relationship of trust

between science and publics more generally, and diminish support and resources available for research of actual value.

All of these concerns are present with respect to stem cells[31] and will be no less so if gene editing becomes the next source of quackery, or if some 'maverick' proves willing to take the most controversial step of using gene editing to create a genetically modified child. While the scientific community in general has been strongly opposed to clinical reproductive uses of gene editing, this does not guarantee that no individual will take this step: some have apparently been willing to make – and report – attempts at that other almost-universally-condemned procedure, human reproductive cloning[32].

Above all, therefore, the ethical, practical and regulatory challenge of gene editing that we need to address is: how we can take steps to prevent 'quack' treatments supposedly based on gene editing from becoming established, how we can avoid as much as possible premature applications of this technology, and how to manage the social consequences if (or perhaps when) this does occur. Furthermore, the transnational market for new health technologies, created by ready access to online information together with medical tourism, makes the global approach that has been called for even more crucial.

Mexico provides an example of how these factors combine to permit the growth of such a market: it and other countries have emerged as potential destinations for patients to obtain ready access to non-proven applications. This has been identified as a key concern in stem cell science[33], with scientists advocating for regulation in order to promote responsibility and prevent the marketing of premature, unproven and potentially harmful interventions in the guise of science[34]. The field of gene editing, as noted, has similarities that if unaddressed may see it go down the same route.

In the third part of this paper, therefore, we move onto considering the prospects and priorities for regulating the use of gene editing technologies. We take the example of Mexico to illustrate some of the issues that will arise, nationally and internationally, as gene editing research moves forward and its potential applications develop.

3. Regulating controversial research: the case of Mexico

The Mexican situation provides an illustration of the consequences of inadequate regulation, while also demonstrating the complex factors – scientific, regulatory, economic and social – that intersect to shape the terrain of science and new health technologies in practice. In this section we examine the Mexican regulatory landscape with respect to biotechnology and its implications for gene editing technologies, both in research and clinical application, and identify challenges that must be addressed.

3.1 Regulation of biotechnology and gene editing in Mexico

Regulatory attention to genetic technologies in Mexico has largely concentrated on genetically modified organisms (GMOs), with a particular focus on biosafety and agriculture. The Inter-Ministerial Commission For Safety of Genetically Modified Organisms (CIBIOGEM) was formed in 2000 to coordinate biosafety policy and oversee all aspects of the production, import, export and use of GMOs[35]. These functions were formalised in 2005 by the Law on Biosafety of Genetically Modified Organisms[36], which was created in order to manage potential risks associated with GMOs and promote the ethical development of this area of biotechnology.

The development of these regulations was influenced by a host of intersecting factors and conflicting interests, particularly related to the Mexican and multi-national biotechnology industry; international trade and economic interests; compliance with international governance; food security; and environmental and biosafety concerns. High on the agenda was the issue of maize, part of Mexico's cultural gastronomic heritage as well as a staple food crop for the region and a major foreign import[35,37]. The Law on Biosafety has itself been criticised as an "essentially symbolic" response to these competing concerns[37], and while we have focused in this paper on human research and applications, it is worth noting that the potential impact of gene editing with respect to agriculture and the environment is likely to propagate and perhaps exacerbate such conflicts.

Significantly, the Law on Biosafety specifically disclaims responsibility for regulating human genetic modification by stipulating that 'human beings' are not

considered 'organisms' for the purposes of the law[36 Article 3(XX)] and excluding from its jurisdiction the human genome, stem cell culture and the modification of human germ cells, stating these to be the province of the General Health Act[38] (GHA) and international treaties[36 Article 6(V)]. As we shall see, however, the GHA and its application, and the other laws that make up the Mexican regulatory landscape, nevertheless leave considerable uncertainty in this area.

While the GHA contains a section on 'The Human Genome'[38 Título Quinto Bis], this mainly concerns the uses of genetic information; genetic modification is not explicitly dealt with. As for the regulation of research on human embryos, gametes and stem cells, this has long been a contested area in Mexico[39]; while the GHA and its associated regulations contain various provisions that might be interpreted to apply, they are very broadly framed, and hence the national regulatory framework remains unclear[40].

At a state level, Mexico City's criminal code[41] contains a few relevant provisions: it proscribes the use of donated gametes for a different end from that established in the donor's consent[41 Article 149], which would seem to permit the use of gametes for scientific research if consent is granted, but fertilisation of eggs for any purpose other than reproduction is forbidden[41 Article 154]. This precludes the creation of embryos specifically for research, which may be important in gene editing work[17,18], but not the use of supernumerary embryos. It prohibits manipulation of human genes "so as to alter the genotype" for any purpose other than eliminating or improving disease[41 Article 154(1)], but it is not clear what is meant by this. It forbids any procedure of genetic engineering for "illicit ends"[41 Article 154(III)], but fails to describe which kind of ends would be licit. There is thus little in the way of specific regulation to govern human gene editing and associated research techniques.

3.2 Regulatory gaps from research to 'therapy': lessons from stem cell science

The legal lacuna in relation to biomedical research and technology presents a problem in many ways. It generates uncertainties for scientists working in

universities and national healthcare research institutions as to whether certain research activities are permitted and to what extent. It may also encourage scientific and medical tourism in order to escape more restrictive laws in other jurisdictions and access treatments unavailable under stricter regulations, as has been the case with stem cell science[42]. Mexico has emerged as a destination for stem cell tourism, leading to the proliferation of unsubstantiated therapies being sold by private clinics in the guise of science: for example, the Regenerative Medicine Institute of Hospital Angeles in Tijuana advertises and markets experimental autologous stem cell treatments as "an alternative to SC therapies not yet approved by the US FDA" [43].

The Mexican situation also demonstrates that in order to be effective, regulation must be sufficiently specific, enforceable and actually enforced. The GHA and its associated regulations explicitly prohibit the commercialisation of human tissues and cells and their derivatives[38 Articles 315-327] and provide that any therapeutic procedures involving these materials must be *gratuitous.* The law also stipulates that healthcare providers and establishments must be licensed and authorised by the Federal Regulatory Commission for Sanitary Risks (COFEPRIS) if they are to administer or conduct experimental medical procedures. However, nothing in the law directly addresses the clinical application of stem cells or stem cell derived products; the terms of the law are vague.

In practice, experimental therapies are easily available and commercialised all over Mexico. The lack of effectively targeted legislation means that operators can escape regulation by switching terms for activities, which also confuses potential patients. For example, although commercialisation of tissues and cells *themselves* is not permitted, operators instead charge for the costs of the procedure, isolation, processing and so on, with the effect in practice of creating a thriving commercial market. This leaves patients exposed to physical and financial burdens and risks when undertaking unregulated stem cell-based therapies, which are widely available. Moreover, the regulatory agency has failed to effectively monitor, supervise and sanction healthcare providers and purveyors of dubious treatments[43]. The ineffective enforcement of the law is

partially explained by the current regulatory authorities lacking compliance mechanisms and the resources, both human and financial, to pursue them, making it difficult to apply existing legal provisions, a situation not helped by the lack of more targeted legislation.

Notwithstanding the legal lacuna with respect to stem cells as such, the relevant law explicitly prohibits the profit-seeking utilisation of tissues and cells. The governance of innovative applications is a "delicate balancing act between minimizing overregulation while still assuring adequate protection of research subjects"[44]. The current *laissez-faire* regime in Mexico, however, has allowed the spread of experimental stem cell treatments, putting at risk patients' wellbeing and giving rise to significant ethical and legal issues[43].

There are important lessons from this for the regulation of gene editing and other forms of biotechnological innovation. In the concluding section, we apply insights from Mexico to suggest considerations for developing regulation for gene editing and other technologies.

4. Conclusions: the way forward?

International regulation of gene editing is something of a patchwork at present with respect to different countries and the various aspects of science involved[45,46]. In some jurisdictions and areas there is little or no regulation; in others, such as Mexico, laws are overly broad or vague, which may make effective implementation difficult; some countries have more developed systems for regulation across relevant areas. A key theme that has emerged from discussions so far, however, is that international cooperation is required to develop and implement appropriate guidelines[17–19]. The need for ongoing discourse and more meaningful engagement is also well recognised. While it is likely that gene editing research, especially on human embryos, will remain controversial, this should not be permitted to lead to regulatory stalemate.

This is equally if not more important when it comes to potential clinical applications. Before any therapies become easily available, it is essential that

they be adequately verified. Medical tourism and internet marketing mean that the problem of unproven treatments transcends national boundaries, and opportunistic providers have shown themselves willing and ready to exploit regulatory differences to profit from patients' desperation. A concerted international approach will be necessary to address this. Cooperation and engagement between and within stakeholder groups is also crucial in order to disseminate accurate information in relation to the current status of clinical applications, and may help in implementing best practice at other levels, such as through professional regulation[47].

With respect to both research and therapy, not just the existence of on-paper regulation but effective mechanisms for oversight and compliance are necessary: regulatory agencies require sufficient power to implement international guidelines and standards in this area. This must be combined with adequate resources, financial as well as human in the form of trained personnel, to monitor the relevant areas of research and health care in order to effectively enforce the legislative provisions adopted. In terms of setting these standards, however, it is also important to promote genuine international discourse that is sensitive to differences in culture, including the culture of science; simply exporting regulatory systems and standards from one region to the rest of the world creates the danger that the principles and values of developed countries will dominate even when they should not.

Additionally, while regulation needs to be sufficiently targeted and specific to be effective, gene editing and genetic modification cannot be the sole focus of our regulatory efforts. If a major concern is to prevent premature clinical reproductive application, then effective oversight of reproductive technologies is also necessary and will complement efforts to control reproductive uses of gene editing. Likewise if we are concerned with the provision of somatic gene therapies, then regulation of the uses of cells and tissues will be important.

Finally, we must recognise and confront the influence of economic interests and unmet health needs, in shaping the regulation of science and innovation, and in creating and sustaining a market for untested, possibly ineffective and/or

dangerous treatments based on emerging biotechnologies. Stringent regulatory hurdles may pose a disincentive for biotechnological development, with scientists and investors threatening to go elsewhere, while countries with more relaxed regulation might be seen as attractive by investors looking for an easy opportunity. Meanwhile, people desperate for cures create a demand for treatments that the market is perhaps too ready to supply, resulting in a new tension between scientists who warn against unproven applications and patients who believe they are being unfairly denied access. A de-regulated health technology market is not the way forward, however, unless we believe profit rather than patient welfare to be the ultimate goal of science.

Attempts to avert the premature application of gene editing in the clinical context must thus form part of a more holistic approach to health technology markets and medical innovation. The same forces and factors that are enabling the market in unproven 'stem cell' treatments to thrive and allowing or even promoting the marketing of other interventions ahead of adequate proof of safety and efficacy, are those which, if not checked, will allow gene editing to go the same way.

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